

## **REMARKS**

### **I. Support for the Amendments to the Specification and the Claims**

Claims 1, 5, and 8 have been amended, and new claims 17-20 have been added. Claims 6, 7, and 13-15 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application. Currently, claims 1-5, 8-12, and 16-20 are pending in the application.

Support for the amendments to the specification and to the claims can be found in the application (including the specification, figures, claims) as originally filed, such as on pages 7-24, in the Examples, and in the original and amended claims. The amendment to claim 5 is technical. The amendment to claim 8 makes the language of claim 8 consistent with the amended language of claim 1.

Support for the amendments to claims 1, 5, and 8 and for new claims 17-20 can be found throughout the specification as originally filed, particularly on pages 7-12. Additional support for the amendments to claim 1 can be found from page 7, lines 21, to page 8, lines 2; on page 8, lines 24-26; from page 9, line 5, to page 12, line 20; from page 13, line 12, to page 15, line 2; from page 18, line 20, to page 19, line 18; on page 28, lines 7-8; and in the Examples. Additional support for the amendments to claim 8 and for new claim 17 can be found, e.g., from page 7, line 23, to page 8, line 2; and in the Examples. Additional support for the amendment to claim 5 and for new claims 19 and 20 can be found, e.g., on page 8, lines 24-26; from page 9, line 5, to page 12, line 20; from page 13, line 12, to page 15, line 2; from page 19, line 29, to page 21, line 2; and in the Examples. Additional support for new claim 18 can be found, e.g., on page 8, line 12; from page 8, line 29, to page 9, line 4; from page 10, line 25, to page 11, line 3; on page 15, lines 3-17; from page 17, line 10, to page 18, line 19; and in the Examples.

## **II. Status of the Claims**

Previously, claims 1-16 were pending in the application. Claims 1, 5, and 8 have been amended, and new claims 17-20 have been added. Claims 6, 7, and 13-15 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application. Currently, claims 1-5, 8-12, and 16-20 are pending in the application.

## **III. The Rejection of the Priority Claim to the Provisional Application is Traversed**

In the previous Office Action, mailed 31 October 2003, the Examiner had acknowledged the priority claim of the present application to a domestic provisional application, presumably U.S. Provisional Application No. 60/175,307 (filed January 10, 2000). Applicants thanked the Examiner for acknowledging the priority claim.

In the present Office Action, mailed 13 August 2004, the Examiner has denied priority claims to any U.S. Provisional Applications, despite the fact that Applicants have claimed priority only of U.S. Provisional Application 60/175,307, filed January 10, 2000. (The other provisional applications were mentioned as describing inventions “related to” the present application. Applicants have submitted an Amendment and two Substitute Specifications with the “related” language removed. U.S. Provisional Application 60/175,307 was filed with a cross-reference paragraph mentioning the other provisional applications and the language was simply included in the present U.S. utility application.)

With respect to U.S. Provisional Application 60/175,307, however, the Examiner states:

The above-noted ‘307 application was submitted to the Office on 10 January 2000 but did not receive a filing date. Accordingly the claim for benefit of priority to the ‘307 application...is DENIED. [Par. 3; p. 3.]

Applicants respectfully traverse the Examiner's rejection of the priority claim of U.S. Provisional Application 60/175,307.

U.S. Provisional Application 60/175,307 was filed on January 10, 2000. On February 14, 2000, a Notice of Incomplete Provisional Application requesting names and residences of inventors was mailed with a two-month deadline for a response. On November 27, 2000, a Petition for Revival of a Provisional Application for a Patent Abandoned Unintentionally was filed. Two Status Inquiries were subsequently filed.

The Office of Petitions granted the Petition for Revival on August 2, 2001. On 15 September 2004, a Withdrawal of Previously Sent Notice and a Filing Receipt were issued. Copies of these three items are enclosed herewith for the Examiner's convenience. The Official Filing Receipt lists an official filing date of January 10, 2000, along with the names and residences of both inventors. The Withdrawal of Previously Sent Notice states:

It has come to the attention of the Office that the Notice on 02/14/2000 was sent in error. Please disregard that Notice.

Therefore, U.S. Provisional Application 60/175,307 has been granted a filing date of January 10, 2000, and the Applicants respectfully assert the priority claim to U.S. Provisional Application 60/175,307, filed January 10, 2000.

#### **IV. The Objection to the Specification is Traversed, but Accommodated in Part**

The Examiner has objected to the specification on several grounds, which will be addressed in separate groups. Some of these objections were previously discussed in the Amendment mailed with the Second Substitute Specification and the Request for Continued Examination on 30 April 2004.

The Request for Continued Examination (RCE) was filed in response to a brief telephone interview with the Examiner on 12 April 2004. During the telephone interview, Applicants' representative noted that Applicants wished to discuss how the situation could be resolved. Because the telephone conference of 12 April 2004 was after a Final Rejection, the Examiner suggested that the case be re-filed so that an interview could be held.

Applicants filed the RCE accordingly. Once again, Applicants respectfully request an interview, notwithstanding the finality of this first Office Action.

Meanwhile, in the present Office Action, the Patent Office alleges:

The [second] substitute specification has NOT been entered as it has been found to contain new matter previously entered and which was objected to in the last Office action. [P. 3, par. 5.]

Applicants respectfully disagree. Because Applicants have made some amendments to the specification, however, Applicants have submitted a Third Substitute Specification based on the previously entered "first" Substitute Specification, which was mailed on 5 March 2003 (return postcard date stamped as having been received on 11 March 2003).

**A. The Objection to the Specification Concerning Incorporation by Reference is Traversed, but Accommodated in Part**

**1. The Objection Alleging Improper Omnibus Language of Incorporation by Reference is Traversed, but Accommodated in Part**

The Patent Office has objected to the specification "as documents have been improperly incorporated by reference" (page 3, par. 6). The Examiner specifically cites the paragraphs at page 49, lines 3-7, and at page 98, lines 3-7, which incorporate "all publications, patents and patent applications mentioned in this specification."

Applicants respectfully disagree for the reasons previously outlined in the Amendment mailed 30 April 2004. Moreover, Applicants note that similar phraseology can be found in many issued patents. In order to further the timely prosecution of the present application, however, Applicants have removed the two paragraphs indicated by the Examiner.

For the reasons outlined above and in the Amendment mailed 30 April 2004, Applicants respectfully submit that the remaining references specifically incorporated by reference meet the requirements of the courts and the Patent Office.

B. The Objection to the Specification on the Grounds under 35 U.S.C. §132 is Traversed, but Accommodated in Part

The Examiner objects to the additions to the specification on pages 20-89, 98-99, and 102 under 35 U.S.C. §132 as introducing new matter. Applicants respectfully disagree.

The Patent Office again quotes *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d 1673, 1679 at length:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. See *General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** See *In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex*

Prods. Co. v. Sun Rubber Co., 274 F.2d 224, 230, 123 USPQ 279, 283 (6<sup>th</sup> Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); cf. Lund, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Par. 1; italics in original; bold emphasis added by Examiner.)

Applicants respectfully traverse the rejection for the reasons noted in the previous Amendment mailed 30 April 2004 and assert that the cases cited by the Examiner are distinguishable from the situation with respect to the present application.

First, it should be noted that in *In re Seversky* (474 F.2d at 673-74), the U.S. Court of Customs & Patent Appeals reviewed three related applications, namely, a “grandparent” application, a continuation-in-part “parent” application, and a continuation-in-part of the parent application, with respect to disclosure of a Venturi gas inlet. The grandparent application disclosed the Venturi gas inlet, but the parent application neither directly disclosed the Venturi gas inlet, nor expressly stated that it incorporated the disclosure of the grandparent by reference. In holding that the Venturi gas inlet of the grandparent application was not incorporated by reference, the court noted that there was “**no ‘incorporation-by-reference’ language whatsoever**” and the “**only relation** to [the grandparent] is indicated by the simple statement **that it is a ‘continuation-in-part’** thereof” (*In re Seversky*, 474 F.2d at 673-74 (bold emphasis added)).

Second, it should be noted that in *In re Lund*, 376 F.2d at 989, the U.S. Court of Customs & Patent Appeals was concerned with whether the Examiner could use an example in the parent application as an anticipatory disclosure of a continuation-in-part patent during prosecution of another patent application when there was neither sufficient disclosure in the CIP application nor an express statement that it incorporated the disclosure of the parent by reference. The Court held that the example disclosed in the parent application was not incorporated by reference for purposes of anticipatory disclosure, stating that “**we do not**

**think that the single sentence by which [CIP applicant] refers to his earlier application – ‘The present application is a continuation-in-part application of our application Serial No. 763,806, filed September 29, 1958 (now abandoned)’ – is sufficient in and of itself to render Example 2 of the abandoned [parent] application part of the patent disclosure as if fully set out therein” (376 F.2d at 989 (emphasis added)).**

Neither of these cases is applicable to the present application. Applicants respectfully assert that the cases cited by the Examiner are distinguishable from the situation with respect to the present application.

The Patent Office further cites MPEP 608.01(p)I, but this is not decisive as the references were incorporated by reference for descriptions of specific methods or substances:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 117 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. [Emphasis added by Examiner.]

Applicants respectfully disagree for reasons already expressed *supra*.

Applicants will address the Examiner’s remarks concerning pages 20-89 first, followed by a discussion of pages 98-99 and 102.

As noted, the incorporation-by-reference statement in the present application is not simply a bald statement of incorporation-by-reference, but rather refers the reader to a method for producing cDNA.

The specification states:

In the practice of the invention, cDNA molecules or cDNA libraries are produced by mixing one or more nucleic acid molecules obtained as described above, which is preferably one or more mRNA molecules such as a population of mRNA molecules, with one or more polypeptides having reverse transcriptase activity under conditions favoring the reverse transcription of the nucleic acid molecule by the action of the enzymes to form one or more cDNA molecules (single-stranded or double-stranded). Thus, the method of the invention comprises (a) mixing one or more nucleic acid templates (preferably one or more RNA or mRNA templates, such as a population of mRNA molecules) with one or more reverse transcriptases and (b) incubating the mixture under conditions sufficient to make one or more nucleic acid molecules complementary to all or a portion of the one or more templates. Such methods may include the use of one or more DNA polymerases. The invention may be used in conjunction with methods of cDNA synthesis such as those described in the Examples below, or others that are well-known in the art [references omitted], to produce cDNA molecules or libraries. **In a preferred embodiment, the cDNA may be produced using the methods detailed in United States patent application serial number 09/076,115 and/or United States provisional application serial number 60/122,395 filed March 2, 1999.** (P. 19, ll. 9-31; bold and underlined emphasis added; references omitted.)

First, unlike the grandparent and parent applications in *In re Seversky* and *In re Lund*, respectively, **the applications cited in the present application are expressly incorporated by reference.** Unlike the incorporation-by-reference statement in the present application, **the “one sentence reference” in *In re Lund* does not include an express incorporation by reference** of the parent application – merely a statement concerning priority.

Second, the incorporation-by-reference statement of the present application is **set forth in a manner generally approved by the USPTO – methods for producing cDNA.** Such a sentence may be found in a great many issued patents, which would have to be invalidated if a more detailed statement were required.

Third, the incorporation-by-reference statement in the present application is not simply a bald statement of incorporation-by-reference, but rather refers the reader to a method for



producing cDNA. In accordance with the MPEP, the references have been identified by their respective numbers and by the subject matter for which they are incorporated.

Further with respect to alleged new matter, Applicants refer the Examiner to the additional arguments concerning other portions of the specification in which cDNA methods were detailed or produced.

Applicants have accommodated the Examiner by deleting material in pages 20-89, which is not specifically directed to methods for producing cDNA.

In view of the foregoing remarks, Applicants respectfully assert that the documents have been not been improperly incorporated by reference. Therefore, Applicants respectfully request reconsideration and withdrawal of the Examiner's objection to the specification.

**If the Examiner's objections to pages 20-89 have not been overcome, Applicants respectfully request that the Examiner contact Applicants' representative to arrange a personal interview.**

Applicants remain confused by the Examiner's continued allegations of new matter with respect to pages 98-99 and 102. In the present Office Action, the Examiner has stated:

As an initial matter, it appears that the presence of multiple versions of a substitute specification may be causing some confusion as to just what is being objected to. The pages that are objected to by the Office are those that are found in the marked copy of the specification submitted on 11 March 2003. [P. 6, par. 13.]

Applicants respectfully submit that in the previous Amendment, mailed 30 April 2004, and in the present Amendment, they were and are referring to the Substitute Specification mailed 5 March 2003 (return postcard date stamped as received on 11 March 2003).

With respect to pages 98-99 of the substitute specification mailed on 5 March 2003 (date stamped as received on 11 March 2003), Applicants wish to draw the Examiner's attention more specifically to a comparison of the paragraph added at page 98, line 23, to page 99, line 18, with the paragraph deleted at page 99, line 18, to page 100, line 13. The Examiner's attention is directed to Table 1, provided for the Examiner's convenience, which shows a side-by-side comparison between these added and deleted sections in the Substitute Specification mailed March 5, 2003. (The Examiner's attention is also directed from page 28, line 23, to page 29, line 17, of the specification as originally filed.) The Examiner will readily note that the "added" paragraphs contain sequence identifiers in compliance with the rules concerning sequence listings, while the "deleted" paragraphs do not. The "additions" were made in an effort to bring the application into conformity with the rules concerning sequence listings. To cancel these paragraphs would remove the sequence identifiers required by the rules.

Table 1.

Added from page 98, line 23, to page 99, line 18 (underlined in Substitute Specification):	Deleted from page 99, line 18, to page 100, line 13 (bracketed in Substitute Specification): <sup>1</sup>
The results of the amplification of nucleic acids stored on solid supports are shown in Figures 2-4. Figure 2 shows the results of the amplification of nucleic acids from HeLa cells. Eluted RNA was precipitated from washes taken from 2-mm punches of HeLa cell samples stored at -20° and -70°C for 1 year as described above. The amplification targets were as follows: Panel A; a 626 bp sequence from b-actin mRNA was amplified using the following thermocycling conditions: 94°C for 1 min, followed by 40 cycles	The results of the amplification of nucleic acids stored on solid supports are shown in Figures 2-4. Figure 2 shows the results of the amplification of nucleic acids from HeLa cells. Eluted RNA was precipitated from washes taken from 2-mm punches of HeLa cell samples stored at -20° and -70°C for 1 year as described above. The amplification targets were as follows: Panel A; a 626 bp sequence from b-actin mRNA was amplified using the following thermocycling conditions: 94°C for 1 min, followed by 40 cycles

<sup>1</sup> See also, from page 28, line 23, to page 29, line 17, of the specification as originally filed.

<p>of 94°C for 30 s; 60°C for 30 s and 72°C for 1.5 min; forward and reverse primer sequences were 5'CCTCGCCTTTGCCGATCC3' (SEQ ID NO: 9) and 5'GGATCTTCATGAGGTAGTCAGTC3' (SEQ ID NO: 10), respectively. Panel B; a 1.08-kb sequence of RPA (replication protein A) mRNA was amplified using the following thermocycling conditions: 94°C for 1 min, followed by 40 cycles of 94°C for 30 s; 55°C for 30 s and 72°C for 1.5 min; forward and reverse primer sequences were 5'CAAGATGTGGAACAGTGGATTTC3' (SEQ ID NO: 7) and 5'CATCTATCTTGATGTTGTAACAAGC3' (SEQ ID NO: 8), respectively. and Panel C: a 5.76-kb sequence of a clathrin-like protein (D21260) mRNA was amplified using the following thermocycling conditions: 94°C for 1 min, followed by 35 cycles of 94°C for 20 s; 60°C for 30 s and 68°C for 7 min; forward and reverse primer sequences were 5'CCCAGTGACAGGAGGAGACCATA3' (SEQ ID NO: 11) and 5'ATCCTGTGCTTTTTCTGTGGGAC3' (SEQ ID NO: 12), respectively. For Panels A and B, Lanes 1-3 and 4-6 are from samples stored at -20°C and -70°C, respectively subsequent to sample application onto FTA® GeneCards, whereas lane 7 is a negative control where SUPERScript II RT was omitted from the RT reaction. Lanes labeled M are a 1 kb ladder size markers. For Panel C, lanes 1, positive control, HeLa RNA, Lanes-2 and 3 are from samples stored at -70°C subsequent to sample application onto FTA® GeneCards,</p>	<p>of 94°C for 30 s; 60°C for 30 s and 72°C for 1.5 min; forward and reverse primer sequences were 5'CCTCGCCTTTGCCGATCC3' and 5'GGATCTTCATGAGGTAGTCAGTC3', respectively. Panel B; a 1.08-kb sequence of RPA (replication protein A) mRNA was amplified using the following thermocycling conditions: 94°C for 1 min, followed by 40 cycles of 94°C for 30 s; 55°C for 30 s and 72°C for 1.5 min; forward and reverse primer sequences were 5'CAAGATGTGGAACAGTGGATTTC3' and 5'CATCTATCTTGATGTTGTAACAAGC3', respectively. and Panel C: a 5.76-kb sequence of a clathrin-like protein (D21260) mRNA was amplified using the following thermocycling conditions: 94°C for 1 min, followed by 35 cycles of 94°C for 20 s; 60°C for 30 s and 68°C for 7 min; forward and reverse primer sequences were 5'CCCAGTGACAGGAGGAGACCATA3' and 5'ATCCTGTGCTTTTTCTGTGGGAC3', respectively. For Panels A and B, Lanes 1-3 and 4-6 are from samples stored at -20°C and -70°C, respectively subsequent to sample application onto FTA® GeneCards, whereas lane 7 is a negative control where SUPERScript If RT was omitted from the RT reaction. Lanes labeled M are a 1 kb ladder size markers. For Panel C, lanes 1, positive control, HeLa RNA, Lanes-2 and 3 are from samples stored at -70°C subsequent to sample application onto FTA® GeneCards,</p>
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HeLa RNA, Lanes-2 and 3 are from samples stored at -70°C subsequent to sample application onto FTA® GeneCards, whereas lane 4 is the negative control.	whereas lane 4 is the negative control.
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With respect to page 102 of the substitute specification mailed on 5 March 2003 (date stamped as received on 11 March 2003), Applicants wish to draw the Examiner's attention more specifically to a comparison of the paragraph added at page 102, lines 8-25, with the paragraph deleted at page 102, line 25, to page 103, line 11. The Examiner's attention is directed to Table 2, provided for the Examiner's convenience, which shows a side-by-side comparison between these added and deleted sections in the Substitute Specification mailed March 5, 2003. (The Examiner's attention is also directed to page 31, lines 13-29, of the specification as originally filed.) Again, the Examiner will readily note that the "added" paragraphs contain sequence identifiers in compliance with the rules concerning sequence listings, while the "deleted" paragraphs do not. The "additions" were made in an effort to bring the application into conformity with the rules concerning sequence listings. To cancel these paragraphs would remove the sequence identifiers required by the rules.

Table 2.

Added at page 102, lines 8-25 (underlined in Substitute Specification):	Deleted from page 102, line 25, to page 103, line 11 (bracketed in Substitute Specification): <sup>2</sup>
Poly(A+)RNA was directly isolated from 2.25 x 10 <sup>6</sup> BHK-21 cells stored on FTA® paper as described above except that the biotinylated oligonucleotide(dT) had special adapter sequences necessary for library construction. The primer includes a <i>Not</i> I recognition site and has the	Poly(A+)RNA was directly isolated from 2.25 x 10 <sup>6</sup> BHK-21 cells stored on FTA® paper as described above except that the biotinylated oligonucleotide(dT) had special adapter sequences necessary for library construction. The primer includes a <i>Not</i> I recognition site and has the

<sup>2</sup> See also, page 31, lines 13-29, of the specification as originally filed.

<p>sequence (Biotin)<sub>4</sub> GACTAGTTCTAGAT CGCGAGCGG CCGCCCTTTTT TTTTTTTTTTTTT TTTTTTTT (SEQ ID NO: 13); (see WO 98/51699 and United States application serial number 09/076,115). As a positive control, poly(A<sup>+</sup>) RNA was isolated total RNA prepared by TRIzol reagent from the same number of cells. Double-stranded cDNA was made and cloned into plasmid vectors as described in WO 98/51699 and United States application serial number 09/076,115. The number of primary clones obtained from the poly(A<sup>+</sup>)RNA was the same whether the mRNA was isolated directly from FTA® or from TRIzol-purified total RNA. The average insert size of the libraries was determined by colony PCR using primers to the plasmid vector. The average insert size for the FTA®-derived material was greater than that for the library constructed from the positive control poly(A<sup>+</sup>)RNA, 1000bp vs 600 bp. This indicates that cDNA libraries of good quality can be made from mRNA isolated directly from samples stored on FTA®.</p>	<p>sequence (Biotin)<sub>4</sub> GACTAGTTCTAGAT CGCGAGCGG CCGCCCTTTTTTTTTTTTTTTTTTTTTTTTTT; (see WO 98/51699 and United States application serial number 09/076,115). As a positive control, poly(A<sup>+</sup>) RNA was isolated total RNA prepared by TRIzol reagent from the same number of cells. Double-stranded cDNA was made and cloned into plasmid vectors as described in WO 98/51699 and United States application serial number 09/076,115. The number of primary clones obtained from the poly(A<sup>+</sup>)RNA was the same whether the mRNA was isolated directly from FTA® or from TRIzol-purified total RNA. The average insert size of the libraries was determined by colony PCR using primers to the plasmid vector. The average insert size for the FTA®-derived material was greater than that for the library constructed from the positive control poly(A<sup>+</sup>)RNA, 1000bp vs 600 bp. This indicates that cDNA libraries of good quality can be made from mRNA isolated directly from samples stored on FTA®.</p>
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Applicants respectfully submit that no new matter has been added to pages 98-99 and 102 by the changes shown in Tables 1 and 2. If the Examiner believes that further additional matter has been improperly introduced, Applicants respectfully request the Examiner to describe the alleged new matter disclosed in these paragraphs more specifically.

Again, Applicants respectfully traverse the Examiner's objections regarding the introduction of new matter into the specification under 35 U.S.C. §132. Therefore, Applicants respectfully request reconsideration and withdrawal of the Examiner's objection to the specification.

**V. Rejection of Claims 1-16 Under 35 U.S.C. § 102(e) (pre-AIPA) Is Traversed in Part and Rendered Moot in Part**

The Examiner has rejected claims 1-16 under 35 U.S.C. 102(e) (pre-AIPA) as being anticipated by Burgoyne (U.S. Patent No. 5,976,572; granted 11/2/99; filed 11/26/97) (paragraphs 14-21). This rejection is rendered moot with respect to claims 6, 7, and 13-15, which have been canceled without prejudice to their pursuit in an appropriate divisional or continuation application. The rejection is respectfully traversed with respect to claims 1-5, 8-12, and 16.

The Patent Office alleges:

16. Burgoyne teaches at length of composition for storage of DNA and RNA, and methods of use. At column 9, fourth paragraph, Burgoyne teaches that RNA that has been immobilized on the matrix is subjected to reverse transcriptase so to synthesize DNA (applicant's cDNA), and that the cDNA can then be used in a variety of assays, including PCR, LCR, and RFLP. The performance of such methods speaks to the cDNA being double stranded in at least one embodiment.

17. Column 3 first full paragraph, teaches that the "composition of the dry solid medium includes a weak base, a chelating agent, an anionic detergent and optionally uric acid or a urate salt."

18. Column 6, fifth paragraph, teaches a plethora of suitable solid supports, including cellulose, nitrocellulose, hydrophilic polymers including synthetic hydrophilic polymers (e.g., polyester, polyamide, carbonate polymers), polytetrafluoroethylene, fiberglass and porous ceramics.

19. Column 6, last paragraph, speaks explicitly of the inclusion of a composition that 'protects against degradation of GM [genetic material; RNA or DNA]'

20. Column 5, second paragraph, teaches a plethora of biological sources from which mRNA can be isolated and stored. Cells, viruses, and preparations

from biological materials are specifically identified (claim 16). [Pars. 16-20; pp. 6-7.]

Applicants respectfully disagree, but have amended claims 1 and 8 in order to further prosecution in a timely manner. Claim 1 currently reads as follows:

1 (currently amended). A method of producing one or more cDNA molecules comprising:

- (a) contacting a sample comprising a cell or a virus with a solid medium, wherein:
  - (i) the cell or the virus comprises mRNA and genomic DNA;
  - (ii) the mRNA comprises an mRNA template of interest;
  - and
  - (iii) wherein the solid medium comprises:
    - a matrix; and
    - a composition for inhibiting degradation of the mRNA template, wherein:
      - the composition is sorbed to the matrix;
      - and
      - the composition comprises a detergent or surfactant;
- (b) sorbing at least a portion of the mRNA template to the solid medium;
- (c) eluting the mRNA from the solid medium while retaining the genomic DNA; and
- (d) contacting the mRNA with one or more reverse transcriptases under conditions sufficient to synthesize one or more cDNA molecules complementary to all or a portion of the mRNA template of interest.

Applicants respectfully submit that the disclosure of Burgoyne does not teach the elution of the mRNA from the solid medium while retaining the genomic DNA, as now claimed in step c of claim 1. Claims 2-5, 8-12, and 16 are dependent on claim 1, either directly or indirectly through one or more intervening claims.

In view of the foregoing remarks, Applicant respectfully asserts that the present invention is not anticipated by Burgoyne. Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 1-5, 8-12, and 16 made under 35 U.S.C. § 102(e).

**VI. Request for Acknowledgement of Information Disclosure Statements**

Applicants have mailed Information Disclosure Statements on 2 October 2001, 26 September 2002, 25 November 2002, and 20 May 2003. Applicants wish to bring these references to the Examiner's attention, along with any references filed concurrently herewith, and respectfully request that the Examiner acknowledge the same. Applicants thank the Examiner accordingly.



## VII. Conclusion

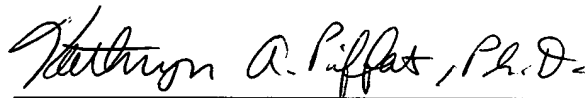
In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

Applicants hereby request a two-month extension of time for the Amendment and accompanying materials. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

Date: January 13, 2005



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